DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS MAIL

APR 3 2001

Mr. Michael King
President
Norbec
P.O. Box 1301
Rancho Murieta, California 95683

Dear Mr. King:

It has come to our attention that your firm is distributing and marketing the Noiselezz Anti-snoring mouth guard to citizens of the United States via the Internet. You should be aware that this product is considered to be a device, as that term is defined by section 201(h) of the Federal, Food, Drug, and Cosmetics Act (Act). Under the FD& C Act, a product is considered to be a medical device if it is used to diagnose or treat a medical condition or to affect the structure or function of the body. Your product, the Noiselezz Anti-snoring guard is promoted to eliminate snoring, which affects the function of the body and as such, it is considered a medical device.

The purpose of this letter is to inform you that under section 510(k) of the Federal, Food, Drug, and Cosmetics Act (21 U.S.C. 360(k)), you are required to notify the Food and Drug Administration (FDA) at least ninety (90) days prior to introduction of a device into commercial distribution in the United States. This requirement is accomplished by the submission of a Premarket Notification requirement (510(k)). This helps protect the public health by ensuring that new medical devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country. The information necessary to comply with the Premarket Notification (510(k)) requirement is found in the Code of Federal Regulations, 21 CFR Part 807, Subpart E- Premarket Notification Procedures. You can also obtain additional information through use of the Internet website http://www.fda.gov.

A review of our records has determined that you did not obtain market clearance before you began offering your device for sale. You should understand that promotion and distribution of the device without submission of Premarket Notification may result in the device being misbranded in accordance with section 502 of the Act. You should also be aware that there are many FDA requirements pertaining to the manufacturing and marketing of medical devices. This letter pertains only to the issue of premarket clearance. It does not necessarily address other obligations you have under the law. As such, you may want to obtain general information about FDA's requirements by contacting our Division of Small Manufacturers Assistance at 1(800) 638-2041.

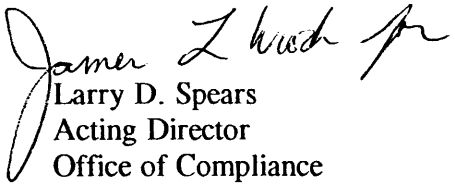
We would appreciate a response within (15) working days from receipt of this letter as to the specific steps you intend to take to achieve compliance with the Act.

Should you have further questions regarding the submission of a Premarket Notification (510(k)), you can contact Ronald L. Swann at (301) 594-4613 x 109.

Your response should be sent to the attention of Mr. Ronald L. Swann, Dental, ENT, and Ophthalmic Devices Branch, at:

US Food and Drug Administration
Dental, ENT & Ophthalmic Devices Branch
2094 Gaither Road, HFZ-331
Rockville, Maryland USA 20850

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health